COLLAMATRIX

JUN 16 2010

510(k) summary
Summary information

K093357
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1. **Date Prepared**

August 1, 2009

2. **Submitter name and address**

Collamatrix Inc.
1F, No.50-1, Keyan Road, Jhunan Science Park,
Miaoli County, 350, Taiwan

3. **Contact person**

Name: Dennis J. N. Seah
Tel: + 886 2 7711 3699
Fax: + 886 2 7711 3599

4. **Device names**

Propriety name: CollaWound ART
Common name: Antimicrobial wound dressing
Classification name: Dressing, Wound

5. **Device classification**

Regulatory class: Unclassified
Product code: FRO

6. **Device description**

CollaWound ART is a wound dressing comprised of collagen and polyhexamethylene biguanide (PHMB). The collagen is prepared from pig skin. CollaWound ART absorbs wound exudates and forms gel-like structure that maintains a moist microenvironment at

the wound bed and aids in granulation tissue formation and re-epithelialization. The dressing acts as a protective barrier to the invasion of foreign microorganisms. The PHMB content is intended to reduce or prevent microbial colonization or growth on the device.

7. **Intended use**

CollaWound ART is a wound dressing intended for use as a barrier to resist microbial colonization within the dressing and reduce microbial penetration through the dressing. CollaWound ART will be used for the management of partial and full thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, wound dehiscence), trauma wounds (abrasions, lacerations, second-degree bums, and skin tears) and draining wounds.

8. **Statement of Substantial equivalence**

CollaWound ART is a PHMB-containing wound dressing device similar to predicate PHMB-containing devices that are previously approved by the agency and allowed for marketing towards the management of wounds.

Predicate devices are listed below

Trade name: FortaDermTM Antimicrobial PHMB Wound Dressing coated with 0.1% Polyhexamethylene Biguanide Hydrochloride (PHMB) (K051647)
Company: Organogenesis Inc.

Trade name: XCell Antimicrobial Cellulose Wound Dressing (K024054)
Company: Xylos® Corporation

The proposed device, CollaWound ART, is another PHMB-containing wound dressing that is quite similar with respect to the indication for use, technological characteristics and material to the above devices in terms of the substantial equivalency under the 510(k) regulations.

9. **Safety and effectiveness**

Biocompatibility tests have confirmed that CollaWound ART meets the requirements

stated in the FDA Blue book memorandum G95-1 and ISO 10993. The following studies were conducted:

(a) Cytotoxicity
(b) Irritation test
(c) Sensitization
(d) Systemic toxicity test
(e) Genotoxicity
(f) Hemocompatibility/hemolysis
(g) Pyrogenic test
(h) Release kinetic
(i) Antimicrobial effectiveness study

10. Conclusion

CollaWound ART is essentially equivalent in indication for use, technological characteristics, material, safety and effectiveness to the commercially available predicate device, and therefore meets the requirements as defined in 21 CFR § 807.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN 16 2010

Collamatrix, Inc.
% Mr. Dennis J.N. Seah
1F, No. 50-1, Keyan Road, Jhunan Science Park
Miaoli County, 350
Taiwan

Re: K093351
Trade/Device Name: CollaWound ART
Regulatory Class: Unclassified
Product Code: FRO
Dated: May 10, 2010
Received: May 14, 2010

Dear Mr. Seah:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of indications for use

510(K) Number (if known): K093351

Device Name: CollaWound ART

Indications for Use:

CollaWound ART is a wound dressing intended for use as a barrier to resist microbial colonization within the dressing and reduce microbial penetration through the dressing. CollaWound ART is intended for the management of wounds including:

- partial and full thickness wounds
- pressure ulcers
- venous ulcers
- diabetic ulcers
- chronic vascular ulcers
- tunneled/undermined wounds
- surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, wound dehiscence)
- trauma wounds (abrasions, lacerations, second-degree burns, and skin tears)
- draining wounds

Prescription Use__X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use_____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MKM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K093351